K090936
#1/2

Section 3 **510(k) Summary**

AUG 25 2009

As required by 807.97
The assigned 510(k) Number is _____

Sponsor	Contec Medical Systems Co., Ltd No. 24, West Huanghe Road Qinhuangdao, Hebei, 066000, China Mr. Li Xueyong, Quality Manager Tel:+86-335-8015490 Fax: +86-335-8015505 Email: lxyong1011@163.com
Submission Correspondent	Ms. Diana Hong / Mr. Tarzan Wang Shanghai Mid-Link Business Consulting Co., Ltd Sute 8D, No.19, Lane 999, Zhongshan No.2 Road(S) Shanghai, 200030, China Tel: +86-21-64264467 Fax: 240-238-7587 Email: diana.hong@mid-link.net
Proposed Product	
Trade Name	ECG MONITOR
Model	ECG80A
Product Code:	DPS
Regulation Number:	21 CFR 870.2340
Device Class:	Class II
Submission Purpose:	New Device
Predicate Device:	Cardiette microtel K082124 Manufactured by: Et medical devices spa Via De Zinis 6, 38011 Cavareno (Trento) ITALY CARDIOLINE AR1200 K051534

	Manufactured by: Et medical devices spa Via De Zinis 6, 38011 Cavareno (Trento) ITALY
Device Description	This product is single channel, standard 12 leads electrocardiograph ,can be widely applied in ECG check-up under different circumstances such as in family ,hospital consultation, doctor's diagnosis, physical check-up， social medical organizations etc. it can implement real time continuous records of clear and exact single-channel ECG waveform using thermo sensitive printer at the same time. waveforms also can be freezed at any time. it has manual and automatic modes to be chosen and Chinese/English operation interface, it is easy to be used.
Test Conclusion	Laboratory testing was conducted to validate and verify that the proposed devices met all design specifications, including electrical safety, EMC, specifications.
SE Determination	The proposed device, ECG80A Single-Channel Handheld Electrocardiograph, is substantially equivalent (SE) to the predicate device Cardiette microtel (K082124) and CARDIOLINE AR1200 (K051534).
Intended Use/Indication for Use	The ECG80A Single-Channel Handheld Electrocardiograph is intended for use in non-invasive recording and displaying ECG waveform of adult patients. In addition, it also can provide to the treating physician with relevant data on the cardiac rhythm in hospital patients. It is immediately available at any time to manually record transient cardiac events, suitable for patient and professional use, helpful in determining the cardiac rhythm at the time of symptoms. This device allows the patient to record their ECG data for displaying or print on the paper. The product is not a conventional diagnostic tool.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 2 5 2009

Contec Medical System Co., Ltd.
c/o Ms. Diana Hong
General Manager
Shanghai Midlink Business Consulting Co., Ltd.
Suite 8D, No. 19, Zhongxin Zhongshan Mansion, Lane 999
Zhongshan No. 2 Road (S)
Shanghai
CHINA 200030

Re: K090936
Trade/Device Name: Single-Channel Handheld Electrocardiograph, Model ECG80A
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: July 21, 2009
Received: July 23, 2009

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090936

Indication For Use

510(k) Number (if known): Pending

Device Name: ECG80A Single-Channel Handheld Electrocardiograph

Indications for Use:

The ECG80A Single-Channel Handheld Electrocardiograph is intended for use in non-invasive recording and displaying ECG waveform of adult patients. In addition, it also can provide to the treating physician with relevant data on the cardiac rhythm in hospital patients. It is immediately available at any time to manually record transient cardiac events, suitable for patient and professional use, helpful in determining the cardiac rhythm at the time of symptoms. This device allows the patient to record their ECG data for displaying or print on the paper.
The product is not a conventional diagnostic tool.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090936